



USAISR TECHNICAL REPORT

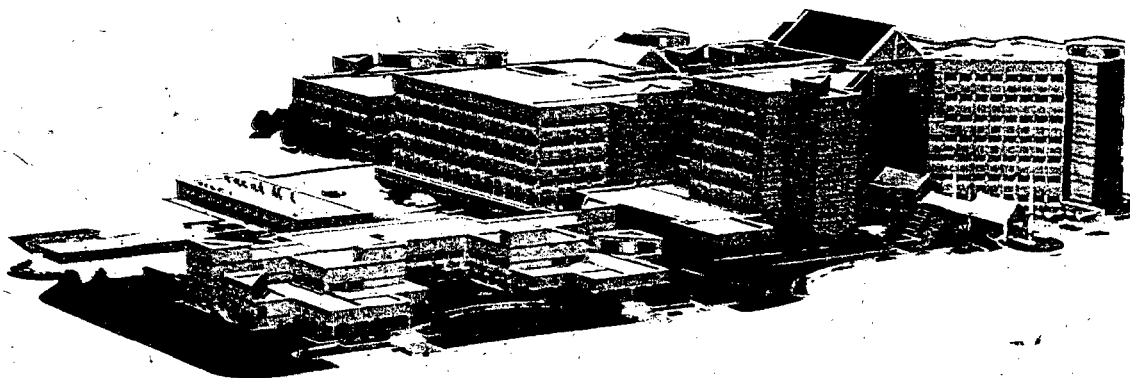
2005-05

Laboratory Evaluation of Battlefield Tourniquets in Human Volunteers

Thomas J. Walters PhD; Joseph C. Wenke PhD; SFC Dominique J. Greydanus, USA; David S. Kauvar MD, MAJ, MC; David G. Baer PhD

DISTRIBUTION STATEMENT A
Approved for Public Release
Distribution Unlimited

September 2005



UNITED STATES ARMY INSTITUTE OF SURGICAL RESEARCH FORT SAM HOUSTON TEXAS

20051202 033



DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3400 RAWLEY E. CHAMBERS AVENUE, BLDG 3611
FORT SAM HOUSTON, TEXAS 78234-6315

REPLY TO
ATTENTION OF

MCMR-USZ-B

3 Oct 2005

MEMORANDUM FOR Commanding General, US Army Medical Research and Materiel Command (MCMR-ZA), 504 Scott Street, Ft. Detrick, MD 21702-5012

SUBJECT: Information Copy of Manuscript

1. The manuscript titled "Laboratory Evaluation of Battlefield Tourniquets in Human Volunteers" by Tom Walters PhD, et al., has been reviewed by this Command and meets acceptable standards for publication. The manuscript contains no matter that warrants disapproval for security or policy reasons.
2. The above manuscript has been submitted to DTIC as a *Technical Report*.

Encl


JOHN B. HOLCOMB
COL, MC
Commanding

CF:
Information Management Division (MCMR-CZ-I)



DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3400 RAWLEY E. CHAMBERS AVENUE, BLDG 3611
FORT SAM HOUSTON, TEXAS 78234-6315

REPLY TO
ATTENTION OF

MEMORANDUM FOR DIRECTOR OF RESEARCH

22 Sep 2005

SUBJECT: Manuscript Review

1. I have reviewed the attached manuscript and appropriate committee approval (IACUC/IRB) titled "Laboratory Evaluation of Battlefield Tourniquets in Human Volunteers" by Thomas Walters PhD, et al. This work represents the results of experiments conducted under:

Title of Protocol: Physiological Evaluation of the One-Handed Tourniquet in Humans

Protocol Number: H-03-002; C.2003.104

Principal Investigator: Victor Convertino PhD

2. The manuscript meets the requirements of good scientific merit.

3. I recommend that the attached manuscript be approved for submission to DTIC and the ISR Library as an ISR Technical Report.

RECOMMENDATION:

APPROVAL/DISAPPROVAL

CHERYL D. DICARLO
LTC, VC
Director of Research

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
<p>The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.</p> <p>PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.</p>					
1. REPORT DATE (DD-MM-YYYY) 30 Sep 2005		2. REPORT TYPE Technical		3. DATES COVERED (From - To)	
4. TITLE AND SUBTITLE Laboratory Evaluation of Battlefield Tourniquets in Human Volunteers				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
				5d. PROJECT NUMBER	
6. AUTHOR(S) Thomas J. Walters PhD; Joseph C. Wenke PhD; SFC Dominique J. Greydanus, USA; David S. Kauvar MD, CPT, MC; David G. Baer PhD				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) U. S. Army Institute of Surgical Research 3400 Rawley E. Chambers Ave. Ft. Sam Houston, TX 78234				8. PERFORMING ORGANIZATION REPORT NUMBER 2005-05	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Objective: To screen currently available commercial off-the-shelf (COTS) tourniquets for effectiveness in human volunteers. Methods: Seven potential battlefield tourniquets were tested for efficacy (elimination of distal Doppler pulse) in the leg (Experiment I; n=18). Those found to be effective in = 80% of subjects in Experiment I were tested on the arm (Experiment II; n=12). Results: Experiment I: Three of the seven tourniquets tested on the thigh were effective in 100% of the subjects tested; a fourth was effective 100% of the time when applied to the arm. Reasons for failure in either test included the inability to occlude arterial flow due to: mechanical limitations (design or construction), circumferential pain, and skin pinching. Conclusion: The Emergency Military Tourniquet™ (Delfi Medical Innovations, Inc.); the Combat Application Tourniquet (Phil Durango LLC); and the Special Operations Force Tactical Tourniquet (Tactical Medical Solutions LLC) were all found to be 100% effective on both the arm and leg in the laboratory environment. Suitability for battlefield use remains to be determined based on field testing.					
15. SUBJECT TERMS Hemorrhage control, extremity trauma, exsanguination, vascular trauma					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unlimited	18. NUMBER OF PAGES 29	19a. NAME OF RESPONSIBLE PERSON Thomas J. Walters PhD
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (Include area code) 210-916-2726

Laboratory Evaluation of Battlefield Tourniquets in Human Volunteers

Thomas J. Walters, Ph.D.; Joseph C. Wenke, Ph.D.; SFC Dominique J. Greydanus, USA;

CPT David S. Kauvar, MC USA; David G. Baer, Ph.D.

US Army Institute of Surgical Research, Fort Sam Houston, TX 78234

Thomas J. Walters, Ph.D.

US Army Institute of Surgical Research

3400 Rawley E. Chambers Avenue

Building 3611

Fort Sam Houston, TX 78234-6315

Telephone: 210/916-2726

Fax: 210/916-8502

Email: thomas.walters@amedd.army.mil

Keywords: Hemorrhage Control; Extremity Trauma; Exsanguination; Vascular Trauma

Abstract.....	2
Introduction.....	3
Materials and Methods	4
Tourniquets	4
Table 1	5
Subjects.....	5
Table 2	6
Experimental Procedures	6
Experiment I	7
Experiment II	8
Data Analysis.....	8
Results	8
Experiment I	8
Table 3	10
Experiment II	10
Table 4	11
Discussion.....	11
Conclusions	17
Acknowledgments	18
References.....	19
Figures	22
Figure 1	22
Figure 2	23
Figure 3	25
Figure 4.....	25
Figure 5.....	27
Figure 6.....	28
Appendix A.....	29

Abstract

Objective: To screen currently available commercial off-the-shelf (COTS) tourniquets for effectiveness in human volunteers. **Methods:** Seven potential battlefield tourniquets were tested for efficacy (elimination of distal Doppler pulse) in the leg (Experiment I; n=18). Those found to be effective in $\geq 80\%$ of subjects in Experiment I were tested on the arm (Experiment II; n=12). **Results:** Experiment I: Three of the seven tourniquets tested on the thigh were effective in 100% of the subjects tested; a fourth was effective in 88%. Experiment II: Three of the four successful devices were effective 100% of the time when applied to the arm. Reasons for failure in either test included the inability to occlude arterial flow due to: mechanical limitations (design or construction), circumferential pain, and skin pinching. **Conclusion:** The Emergency Military Tourniquet™ (Delfi Medical Innovations, Inc.); the Combat Application Tourniquet (Phil Durango LLC); and the Special Operations Force Tactical Tourniquet (Tactical Medical Solutions LLC) were all found to be 100% effective on both the arm and leg in the laboratory environment. Suitability for battlefield use remains to be determined based on field testing.

Introduction

The majority of combat wounds occur in the extremities, and it has been estimated that 7 out of 100 battlefield deaths could be prevented with properly applied tourniquets (1, 2). The need for a rapidly deployable military tourniquet has been identified for at least half a century (3), and recently it has been recommended by military medical experts that high priority be given to the development of an improved, field-expedient tourniquet capable of reliably stopping arterial bleeding as well as rapid self-application with one hand (4). Rather than spending time attempting to develop the ideal military tourniquet, it was decided to screen currently available commercial off-the-shelf (COTS) devices. The availability of candidates was based on an informal internet search for trauma tourniquets which revealed a number of possible COTS candidates, as well as reports from military medical personnel involved in Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) of the use of commercially available tourniquets in recent combat. Appropriate functional parameters, design criteria, and testing procedures were specified by an expert panel convened as part of the 2003 Advanced Technology Applications for Combat Casualty Care Conference (ATACCC)(5). An ad hoc committee at this meeting combined design parameters along with previously established limits on cost, weight, physical size, and effectiveness.(6) The consensus of this committee was used as the basis of a Request For Information (RFI) requesting letters of intent from parties interested in producing tourniquets for testing. The RFI was posted in Federal Business Opportunities (www.FedBizOpps.gov) (Appendix A). Interested parties were asked to provide 10 units of their proposed battlefield tourniquet for testing in human subjects at the United States Army Institute of Surgical Research (USAISR). Nine companies responded to the RFI with candidate

devices and this paper reports the results of testing these candidates in human volunteers.

Materials and Methods

Tourniquets

Nine different tourniquet models were submitted for testing, and seven of these met design criteria. Their size, weight, and design features are shown in Table 1. Tourniquets failing to meet one or more design requirements were excluded from further evaluation in human subjects. The candidates were as follows: Combat Application Tourniquet (CAT-Phil Durango, LCC); Self-Applied Tourniquet System (SATS-Marketing Tactics, LLC); Mechanical Advantage Tourniquet (MAT-Bio Cybernetics International); Special Operations Forces Tactical Tourniquet (SOFTT-Tactical Medical Solutions, LLC); One Handed Tourniquet (H-dyne-Hemodyne Inc.); Last Resort Tourniquet (LRT-Hammerhead, LLC); Emergency Military Tourniquet (EMT-Delfi Mecial Innovations Inc.); London Bridge Tourniquet (LBT-London Bridge Trading Company, LTD); K² Tactical Tourniquet (K² -HG WV, LLC).

Table 1

Tourniquet	Wt (g)	L (cm)	W (cm)	H (cm)	LxWxH (cm)	Strap Width (cm)	Maximum Circumference (cm)	Mechanical Augmentation
CAT	59	18.3	4.8	3.1	266	3.8	77	Windlass
SATS	136	16.5	4.8	5.7	448	3.8	122	Cam
MAT	145	12.1	10.4	7.2	912	3.8	88	Block and Tackle
SOFTT	160	17.4	5.1	8.4	746	3.7	93	Windlass
H-dyne	174	25.0	4.8	5.8	692	2.8	83	Elastic
LRT	183	10.9	6.0	6.3	410	5.1	76	Ratchet
EMT	215	10.3	6.9	6.9	491	9.1	89	Pneumatic
LBT	260†	14.7	5.5	4.9	401	2.4*	89	Ratchet
K ²	990†	47.6	3.8	25.4	4,597	3.8	78	Ratchet

Physical characteristics of candidate tourniquets. Abbreviations: CAT- Combat Application Tourniquet (Phil Durango, LCC); SATS – Self-Applied Tourniquet System (Marketing Tactics, LLC); MAT – Mechanical Advantage Tourniquet (Bio Cybernetics International); SOFTT – special operation forces tactical tourniquet (Tactical Medical Solutions, LLC); H-dyne – One Handed Tourniquet (Hemodyne Inc.); LRT – Last Resort Tourniquet (Hammerhead, LLC); EMT – Emergency Military Tourniquet (Delfi Mecial Innovations Inc.); LBT – London Bridge Tourniquet (London Bridge Trading Company, LTD); K² - K² Tactical Tourniquet (HGWV, LLC).

Subjects

Following approval from the Brooke Army Medical Center Institutional Review Board, two separate experiments were conducted. Tourniquets were tested at the level of the proximal femur in Experiment I and the proximal humerus in Experiment II. After being informed of all

procedures and risks, twenty healthy, normotensive, men and women age 23-47 years gave written consent to serve as subjects in one or both experiments. Eighteen subjects participated in Experiment I (16 male, 2 female). Twelve subjects participated in Experiment II (10 male, 2 female). Ten of the subjects in Experiment II had also participated in Experiment I.

Both experiments were conducted with the subjects wearing surgical "scrubs" of identical fabric composition. Prior to the experiment, each subject's height, weight, limb circumference (Experiment I mid-thigh; Experiment II mid-upper arm) was measured. The subjects were then seated and upper extremity blood pressure and heart rate were measured. Baseline subject data are presented in Table 2.

Table 2

	Experiment I - Leg		Experiment II - Arm	
	(n = 18)		(n = 12)	
	Mean \pm SD	Range	Mean \pm SD	Range
Age (yrs)	35.3 \pm 7.3	23-47	35.5 \pm 7.9	22-47
Weight (Kg)	83.4 \pm 10.7	65-103	85.5 \pm 13.9	65-103
Height (cm)	177 \pm 7	163-188	178 \pm 8	163-191
Limb Circumference (cm)	59.5 \pm 4.6	51.5-67.5	34.0 \pm 4.2	28.5-42.5
Heart Rate (beats/min)	65 \pm 9	42-80	62 \pm 7	50-72
Blood Pressure (mmHg)				
Systolic	122 \pm 7	100-130	119 \pm 6	110-128
Diastolic	75 \pm 9	58-90	79 \pm 4	70-88

Baseline characteristics of subjects. Subject data for male and female subjects is combined: Experiment I - 2 female, 16 male; Experiment II - 2 female, 10 male.

Experimental Procedures

All tourniquets were tested in a single session with each subject. Each tourniquet was assigned a number, and this number was used in conjunction with a random number generator to produce the order of testing for each subject. The primary endpoint of both experiments was the elimination of arterial blood flow in the popliteal (Experiment I) or radial (Experiment II) artery, determined using Doppler ultrasound (Imexdop CT+, Nicolet Vascular Inc.) which provided the investigators and subjects with continuous auditory feedback during the tightening of each tourniquet. Prior to testing each tourniquet, subjects were instructed on how to properly apply each device according to the instructions provided by the manufacturers. Subjects applied and tightened their own tourniquets, and were instructed to continue tightening the tourniquet until either the audible Doppler signal ceased or the pain from the tourniquet became intolerable. If the subject successfully occluded blood flow, the tourniquet was slowly released to confirm re-establishment of Doppler signal and ensure that loss of signal was due to the tourniquet and not movement of the ultrasound probe. Subjects were aided by the experimenter to ensure proper and uniform placement prior to tightening each tourniquet.

In some cases tourniquets broke or malfunctioned during a test. In these cases, the event was noted and the subject was asked to repeat the test with a new, identical tourniquet. Immediately upon release of each tourniquet subjects rated the pain produced during tourniquet application using the visual analog pain scale.⁽⁷⁾ Subjects were asked to differentiate between diffuse, circumferential pain from the tourniquet strap and localized pinching from one or more tourniquet components.

Experiment I

With the subject seated, the site of maximal popliteal Doppler signal at the level of the knee was located and marked. The subject positioned the tourniquet around their proximal thigh and

secured it in place. The experimenter then re-established a Doppler signal, and the subject tightened the tourniquet. Subjects alternated between right and left legs, with 5 minutes between each test. The initial leg was alternated between each session, e.g., subject 1 applied the first tourniquet to the right leg, subject 2, to the left. All tourniquets meeting design criteria were tested in Experiment I. Tourniquets were required to occlude arterial flow in 15 of the 18 (83%) of the subjects to be considered successful and be tested in Experiment II.

Experiment II

With the subject seated, the site of maximal radial arterial signal at the level of the wrist was located by Doppler auscultation and marked. Following instruction, the subject applied the tourniquet to their non-dominant arm. All other procedures were the same as those outlined in Experiment I.

Data Analysis

Data from the analog pain scale was analyzed using a Cochran-Mantel-Haenszel Chi-square Test. Significance was set at $p < 0.05$. Tourniquets were judged effective if they were successful in occluding arterial flow in $\geq 80\%$ of subjects, which is the military standard for tourniquet effectiveness(8). No statistical analysis was applied to the effectiveness data.

Results

Experiment I

The results of Experiment 1 are shown in Table 3. The CAT, EMT, and SOFTT were effective in all subjects. The MAT was effective in 88% (14/16). The remaining three tourniquets all fell below the 80% level of acceptance. Mechanical failures occurred in two of the devices tested; 4 MAT tourniquets and 3 LRT tourniquets. In these cases, the trial was repeated with a replacement tourniquet, and breakage is not reflected in the effectiveness data. Pain scores were

only analyzed for tourniquets that met the acceptance level based on the elimination of Doppler pulse, i.e., the MAT, EMT, CAT, and SOFTT. The EMT resulted in significantly decreased circumferential pain than the other three effective tourniquets ($p < 0.05$). Pinching was significantly decreased in both the EMT and CAT compared to the remaining two ($p < 0.05$). In the event that a tourniquet failed to eliminate Doppler pulse, the reason for the failure was noted (Table 3). The causes of failure were: intolerable pain, either circumferential or pinching; failure of the tourniquet to maintain tension (slipping); or the inability of the subject to generate the requisite tension (physical limitation).

Table 3

	MAT	CAT	EMT	LRT	H-Dyne	SATS	SOFTT
Percent Effective	88	100	100	67	22	44	100
Number Effective	14/16	18/18	18/18	12/18	4/18	8/18	18/18
Pain (circumferential)	n/a	3.1	2.6*	n/a	n/a	n/a	3.5
Pain (pinch)*	n/a	0.4†	0.0†	n/a	n/a	n/a	2.2
Reason for Failure							
Pain (circumferential)	1	n/a	n/a	2	4	2	n/a
Pain (pinch)	1	n/a	n/a	1	0	0	n/a
Slipping	0	n/a	n/a	3	5	0	n/a
Physical limitation	0	n/a	n/a	0	5	8	
Malfunction/Break	4	0	0	3	0	0	0

Results of Experiment I. *Significantly different from CAT and SOFTT ($p < 0.05$)

†Significantly different from SOFTT ($p < 0.05$)

Experiment II

The results of Experiment 2 are shown in Table 4. Three tourniquets were effective in all subjects tested. A fourth, the MAT, was effective in 75% (9/12). The failure of the MAT was due in all cases to intolerable pinching pain. The MAT produced significantly greater pinching pain than the other tourniquets ($p < 0.05$). If the subject was unable to achieve successful occlusion, the pain score for this subject was excluded from the analysis.

Table 4

	MAT	CAT	EMT	SOFTT
Percent Effective	75	100	100	100
Pain (circumferential)	2.0	1.0*	0.0*	0.5
Pain (pinch)*	6.5	0.0*	0.0*	2.5
Malfunction/Break	4	0	0	0

Results of Experiment II. *Significantly different from EMT and CAT ($p < 0.05$)

Discussion

The results of this study are significant in that we have not only identified three effective COTS battlefield tourniquets, but we also have identified a number of ineffective devices. The latter point is arguably as important as the first. The primary objective in the use of a tourniquet is complete arterial blood flow occlusion in order to cease more distal hemorrhage. A device that delivers anything short of this is unacceptable (5, 9). A tourniquet tight enough to occlude venous but not arterial flow can exacerbate hemorrhage from injured arteries and cause significant injury to underlying and distal tissues. An inadequate tourniquet can also cause significant bleeding from damaged soft tissues distal to the device by allowing continued arterial flow to these tissues with occlusion of venous return to the circulation. In this circumstance, venous flow will be primarily through damaged tissue.

The limb circumferences for the 2 female subjects in Experiment I fell into the 50th percentile for U.S. male soldiers, so we combined all data into a single group. The overall range of limb circumferences was 51.5-67.5 cm, corresponding respectively to the 95th and 5th

percentiles of U.S. male soldiers (10). A more rigorous test would have included subjects with thigh circumferences at or near the upper extremes of male soldiers, however we felt that it would prove excessively difficult to screen only for subjects representing the upper extremes and would preclude the identification of tourniquet design problems that affected only smaller limbs. In testing of the three tourniquets that were successful in all subjects, 7 of 18 subjects had thigh circumferences above the 80th percentile of U.S. Army personnel.

The majority (68%) of combat injuries requiring a tourniquet occur in the lower extremities (11). The lower limb requires much greater tourniquet pressure to occlude blood flow than does the upper limb because the pressure required to occlude blood flow in a limb increases exponentially with limb circumference (12-14). We initially thought that testing could be limited to the lower limbs because it is much more difficult to occlude their arterial flow, however we were concerned that unique design features of individual tourniquets might preclude effectiveness at the smaller circumferences of the arm. While this was not an issue with the three tourniquets that worked in all subjects, it was a problem with the MAT. Specific features of this device's design resulted in skin pinching so severe that 3 of the 12 subjects were unable to tighten the tourniquet to occlusion pressure. While it is not possible to conclude that the MAT would have been effective had this not been the limiting factor, it is nonetheless likely based on the fact that it was effective 82% of the time in the inherently more difficult test in Experiment I. This device may be amenable to structural modifications which would resolve this problem.

There was no subject that reported difficulty tightening the CAT and it is likely that additional tightening would have been possible in all subjects if required. Likewise, the EMT easily reached occlusion pressure in all subjects. In contrast, the SOFTT had much less "reserve" tightening capacity. We found prior to formal testing that it was necessary to pull the

SOFTT very snug (through the buckle) prior to tightening with the windlass. This was because only 2 turns of the windlass could be obtained before the bulk of the strap began to hinder further tightening. Consideration of reserve tightening capacity may be significant for those interested in use of these devices in the field, where use will be under less ideal conditions.

The CAT (**Figure 1**) and SOFTT (**Figure 2**) use a windlass for tightening which can be fixed in one of two positions separated by 180°. In the present investigation subjects were instructed to tighten each tourniquet until they were unable to hear a Doppler pulse, but were not required to secure the windlass. Under actual use, the requirement to fix the windlass could force the user to tighten the tourniquet more than what was required in the current experiment. Each ½ turn of the windlass resulted in a take up of approximately 4.5 cm and 7.0 cm for the CAT and SOFTT, respectively. In contrast the EMT, because it is pneumatic (**Figure 3**), can be tightened (inflated) in very small increments. Thus it is safer due both to its greater width, as well as the ability to more finely adjust pressure.

The pressure profile between a tourniquet and underlying tissue is less damaging in inflatable than strap tourniquets. The shear force caused by the abrupt edge of a strap results can result in direct trauma to underlying nerves (15-17). A unique feature of the CAT involves placing the tightening strap within a sleeve, a “strap within a strap” design (**Figure 1**). Although not directly tested in the present study, this appeared to have the effect of more evenly distributing the circumferential force around the limb.

Statistical analysis of pain scores could not be performed using unsuccessful trials as their inclusion would represent an underestimation of pain; i.e., a successful trial would require greater tightening pressure and thus greater pain. Analysis was therefore performed only on the four tourniquets meeting the criteria for success ($\geq 80\%$ effectiveness). The EMT produced

significantly less circumferential pain in both the leg and the arm than other devices. Combined with the established relationship between tourniquet width and effective occlusion pressure (13), and the pain scores in the present study, it is reasonable to assume that the elimination of Doppler pulse with this device occurred at a lower pressure than the other tourniquets tested. Animal studies have demonstrated that there is a direct relationship between nerve injury and tourniquet pressure (16, 18) and the majority of nervous complications following tourniquet use during extremity surgery can be attributed to the accidental overinflation of the tourniquet (19). For these reasons it is likely that the EMT represents the safest tourniquet tested, and it is the only device that has been systematically tested as a hemorrhage control device during surgery (20).

This study has not only determined which battlefield tourniquets are effective and should be considered for fielding, but also determined which tourniquets are ineffective and/or suffer from apparently flawed engineering. Of the nine tourniquets received for testing, six are currently commercially available (CAT, SATS, SOFTT, LRT, EMT, LBT) and three are advanced prototypes (MAT, OHT, K²) intended for eventual commercial marketing. Strap type tourniquets do not require approval from the U.S. Food and Drug Administration (FDA) as a medical device, and this study is the first systematic, laboratory evaluation of non-pneumatic tourniquets in human subjects. The pneumatic EMT has been tested in humans and does have FDA approval (20).

Nine companies originally responded to RFI with devices; however two of their submissions failed to meet minimum design requirements. One of the rejected devices exceeded weight and size limits (K²), while the other failed to meet the minimum strap width requirement of 1 inch (LBT). This minimum was required for the safety of human subjects as the force

required to occlude blood flow is inversely proportional to the tourniquet width (13), and the severity of tourniquet injury is directly proportional to tourniquet pressure (16, 21).

The SATS was effective in only 44% of the subjects (**Figure 4**). The cam used to mechanically enhance tightening provided only 3.9 cm of excursion. This forced the majority of the tightening to be performed through the strap and buckle. In subjects in whom the SATS was effective, repeated releases of the cam and retightening through the buckle were required before occlusion was obtained. In 50% of the subjects this measure was not adequate to obtain occlusion.

The H-dyne tourniquet was the least effective tourniquet tested, with occlusion reached in only 22% of subjects. It is composed of four parallel 3/8 inch “bungee” cords, and at a width of 2.8 cm it was the narrowest tourniquet tested. A cross section composed of four round cords is not comparable to a strap of a similar cross section as the effective reduction in the diameter of each cord as it stretched during application was observed to result in a considerably narrower overall width. This fact likely contributed to the failure of the device because there is an inverse relationship between tourniquet width and the circumferential force required to occlude arterial flow in a limb(13). This may explain why five subjects were unable to generate the requisite force to eliminate Doppler pulse with the consistently narrowing bands. The greater circumferential force results in greater pain, explaining why four additional subjects failed to occlude flow before the pain became intolerable. The remaining five failures were due to slippage of the cords through the buckle. This was likely due to the fact that in order to have a safe device, we needed to remove the metal serrated plate designed to grip the cords as they passed through the buckle because these plates were flawed in the tourniquets we received, making it impossible to loosen the tourniquet once it was tightened (**Figure 5**). Thus the H-dyne

tourniquets we tested were altered from the manufacturer's design. Regardless, even if this had not been the case, this tourniquet would have failed based on the other issues discussed above.

Malfunctions were observed in two of the tourniquets; the MAT (**Figure 6**) and LRT (**Figure 7**). In the case of the MAT, the tightening mechanism broke on four tourniquets (22%). The malfunction was similar in every case, at the time of this writing this problem had been solved by the manufacturer. In the case of the LRT two major types of malfunction occurred. In four tourniquets the latching mechanism simply fell out, rendering the tourniquet useless. In all cases this occurred prior to application, so no test was directly affected by these malfunctions. However on four other occasions during testing, the ratchet was unable to engage once significant tension was placed on it. This was because excessive play of the ratchet wheel within the race caused the ratchet to disengage from the pawls when under tension, making it incapable of generating additional force. A tourniquet based on a similar ratchet mechanism has been included in the U.S. Army Ranger's hemorrhage control kit and has proven to be effective in use on the battlefield. Failure in laboratory testing highlights the importance of testing even those designs which appear to be reasonable for use. It is possible that other tourniquets, both improvised and purpose-built, which also appear to be sufficient upon cursory inspection, might fail under rigorous testing.

In the present study intolerable pain was one criterion for failure. The use of pain as a criterion for success could be argued as an unfair test of a tourniquet's effectiveness in a battlefield situation, in which pain is a secondary concern after hemorrhage control. On the other hand one could speculate that the extent of tourniquet pain induced by a given tourniquet is related to the potential for compression injury to the underlying nerve, thus self-limitation acts as an indirect screen for the safety of a given tourniquet. In any case, we are unaware of an ethical

method of inducing normal volunteers to apply extremely painful and potentially injurious tourniquets to occlusion pressure. It is noteworthy that with the exception of the H-dyne, no tourniquet was eliminated based on pain alone.

It is important to note that we made no attempt to simulate field conditions. Potential interactions of field clothing, challenging environmental conditions, and other battlefield concerns with tourniquets remain to be evaluated. Additionally, materials testing will also be required to ensure that mechanical components are not vulnerable to extremes in temperature or other environmental changes.

Conclusions

Given that many of the tourniquets that we tested are or soon will be available for purchase by individual soldiers and units; providing guidance on which devices are and are not effective is important and timely. Tourniquets for battlefield use have received significant interest from field healthcare providers as well as soldiers in other military specialties. As a result, the fielding of effective, safe, simple, and field-expedient tourniquets has been identified as a high priority by Department of Defense medical commands. The Emergency Military Tourniquet (EMT) (Delfi Medical Innovations, Inc.); the Combat Application Tourniquet (C-A-T)(Phil Durango LLC); and the Special Operations Force Tactical Tourniquet (SOFTT) (Tactical Medical Solutions LLC) were found to be 100% effective on both upper and lower extremities in the laboratory environment. The strategy of identifying and testing COTS devices should significantly expedite the fielding of an effective battlefield tourniquet, however final recommendations await field and materials testing.

Acknowledgments

We thank Ms. Heather Wynne and Ms. Angelica Torres for their valuable technical assistance. This work was funded by the United States Navy Office of Naval Research.

References

1. Mabry RL, Holcomb JB, Baker AM, et al. United States Army Rangers in Somalia: an analysis of combat casualties on an urban battlefield. *J Trauma* 2000;49(3):515-28; discussion 28-9.
2. Bellamy RF. The causes of death in conventional land warfare: implications for combat casualty care research. *Mil Med* 1984;149(2):55-62.
3. Mallory M. Emergency Treatment and Resuscitation at the Battalion Level. *Recent advances in Medicine and Surgery* 1954;1:61-7.
4. Butler FK, Jr., Hagmann JH, Richards DT. Tactical management of urban warfare casualties in special operations. *Mil Med* 2000;165(4 Suppl):1-48.
5. Walters TJ, Mabry RL. Issues Related to the use of Tourniquets on the Battlefield. *Mil Med* In Press.
6. Wenke JC, Walters TJ, Greydanus DJ, Pusateri A, Covertino VA. Physiological Evaluation of the One-Handed Tourniquet. *Mil Med* In Press.
7. Wong D, M H-E, D W, ML W, P S. Wong's Essentials of Pediatric Nursing. 6 ed. St. Louis: Mosby, Inc.; 2001.
8. Calkins D, Snow C, Costello M, Bentley TB. Evaluation of possible battlefield tourniquet systems for the far-forward setting. *Mil Med* 2000;165(5):379-84.
9. Wolff LH, Adkins TF. Tourniquet Problems in War Injuries. *The Bulletin of the US Army Medical Department* 1945;37:77-84.
10. Gordon CC, Churchill T, Clauser CE, et al. Anthropometric Survey of U.S. Army Personnel: Methods and Summary Statistics 1988. Technical Report. Natick,

Massachusetts: United States Army Natick Research, Development, and Engineering Center; 1989 March 24, 1989. Report No.: Natick/TR-89/044.

11. Lakstein D, Blumenfeld A, Sokolov T, et al. Tourniquets for hemorrhage control on the battlefield: a 4-year accumulated experience. *J Trauma* 2003;54(5 Suppl):S221-5.
12. Crenshaw AG, Hargens AR, Gershuni DH, Rydevik B. Wide tourniquet cuffs more effective at lower inflation pressures. *Acta Orthop Scand* 1988;59(4):447-51.
13. Graham B, Breault MJ, McEwen JA, McGraw RW. Occlusion of arterial flow in the extremities at subsystolic pressures through the use of wide tourniquet cuffs. *Clin Orthop* 1993(286):257-61.
14. Shaw JA, Murray DG. The relationship between tourniquet pressure and underlying soft-tissue pressure in the thigh. *J Bone Joint Surg Am* 1982;64(8):1148-52.
15. Hodgson AJ. A proposed etiology for tourniquet-induced neuropathies. *J Biomech Eng* 1994;116(2):224-7.
16. Ochoa J, Fowler TJ, Gilliatt RW. Anatomical changes in peripheral nerves compressed by a pneumatic tourniquet. *J Anat* 1972;113(3):433-55.
17. Pedowitz RA, Nordborg C, Rosenqvist AL, Rydevik BL. Nerve function and structure beneath and distal to a pneumatic tourniquet applied to rabbit hindlimbs. *Scand J Plast Reconstr Surg Hand Surg* 1991;25(2):109-20.
18. Nitz AJ, Dobner JJ, Matulionis DH. Pneumatic tourniquet application and nerve integrity: motor function and electrophysiology. *Exp Neurol* 1986;94(2):264-79.
19. Kam PC, Kavanagh R, Yoong FF, Kavanaugh R. The arterial tourniquet: pathophysiological consequences and anaesthetic implications. *Anaesthesia* 2001;56(6):534-45.

20. McEwen JA, Inkpen K. Surgical Tourniquet Technology Adapted for Military and Prehospital Use. In: Combat Casualty Care in Ground Based Tactical Situations: Trauma Technology and Emergency Medical Procedures; 2004: NATO publication; 2004. p. 19.1-.2.
21. Nitz AJ, Matulionis DH. Ultrastructural changes in rat peripheral nerve following pneumatic tourniquet compression. J Neurosurg 1982;57(5):660-6.

Figures

Figure 1

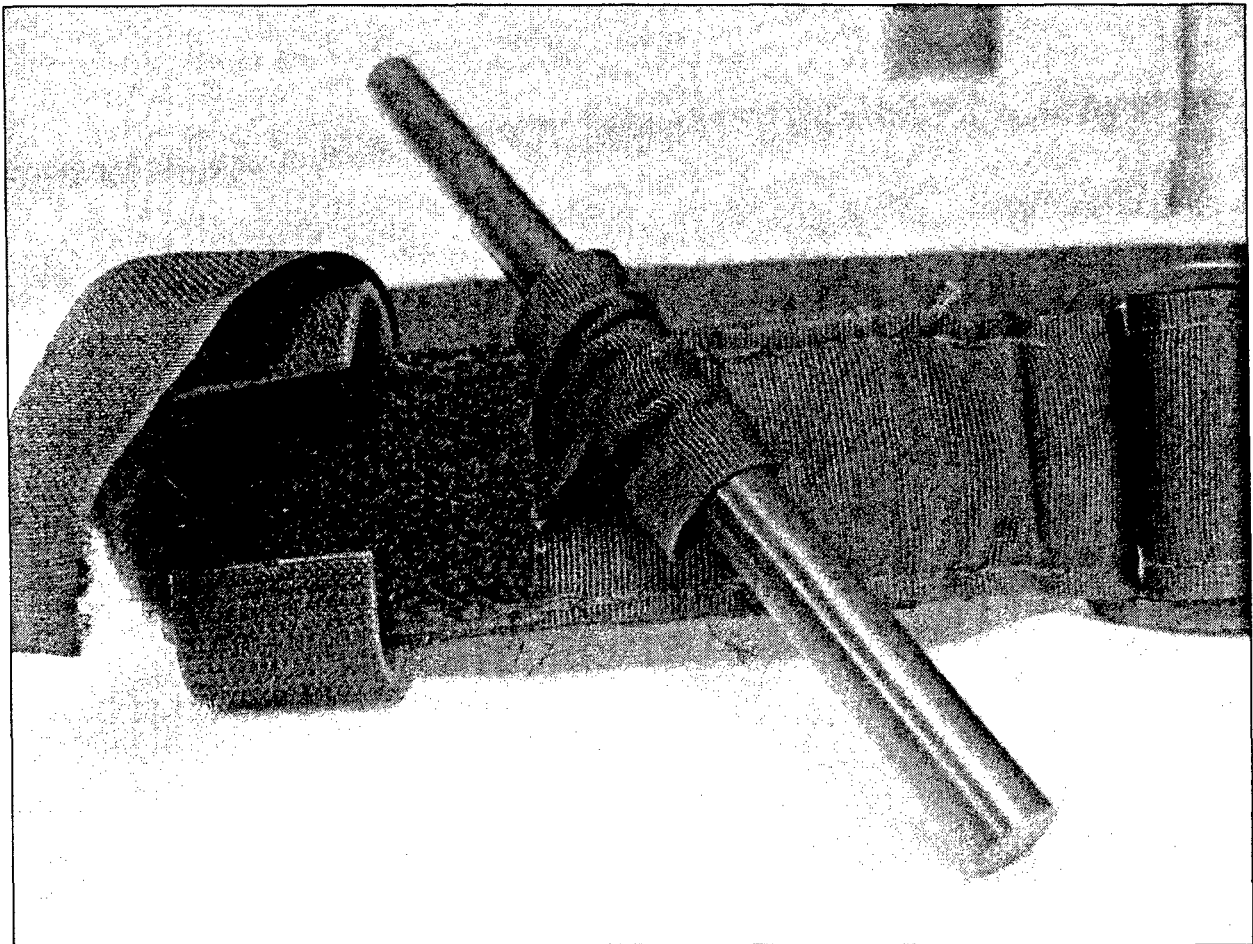


Figure 1. The Combat Application Tourniquet (Phil Durango). The rod acts as a windlass, tightening the inner strap within the outer sleeve with each turn. The strap on the left secures the windlass when the tourniquet is fully tightened.

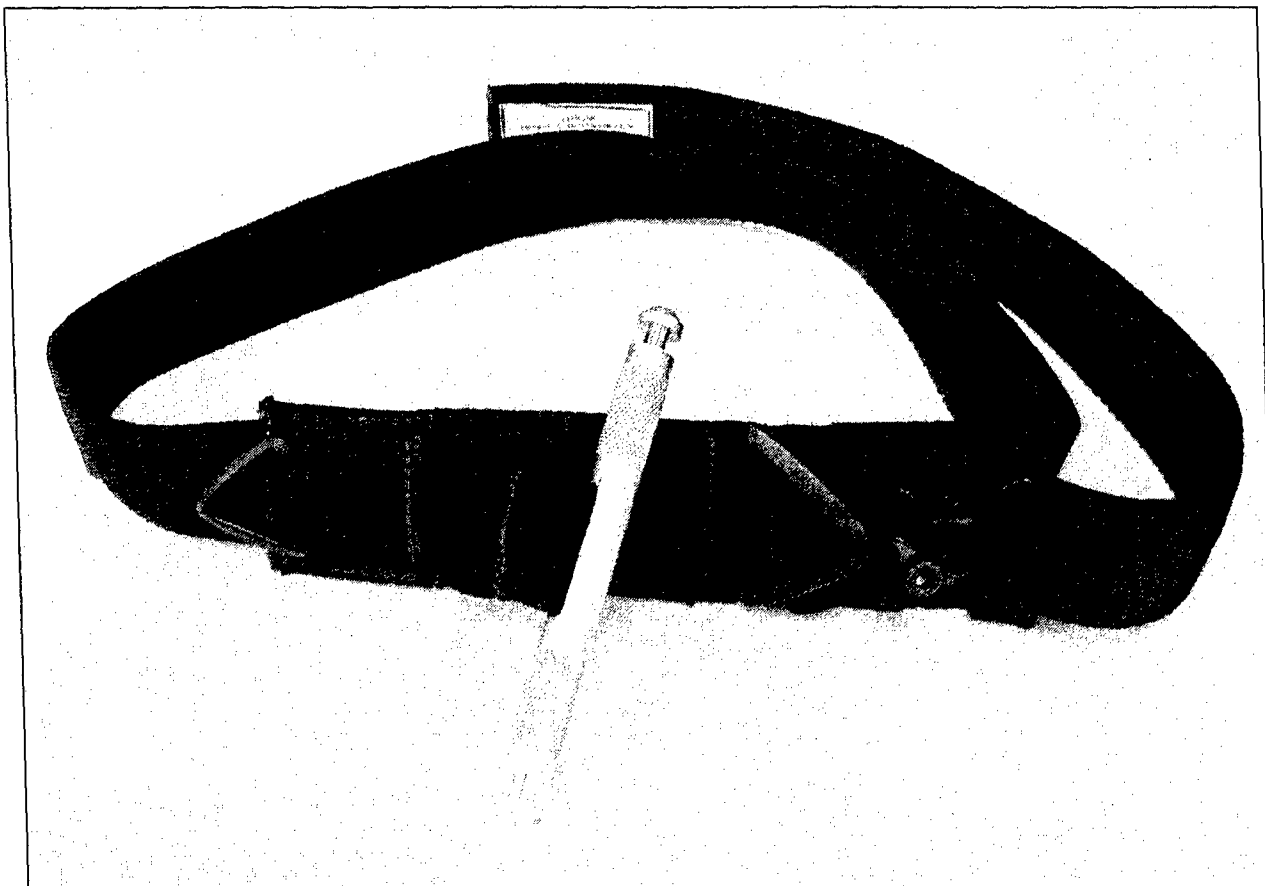
Figure 2

Figure 2. The Special Operations Forces Tactical Tourniquet (Tactical Solutions). The silver rod acts as a windlass, tightening the entire strap. The triangular pieces secure the windlass when the tourniquet is fully tightened.

Figure 3

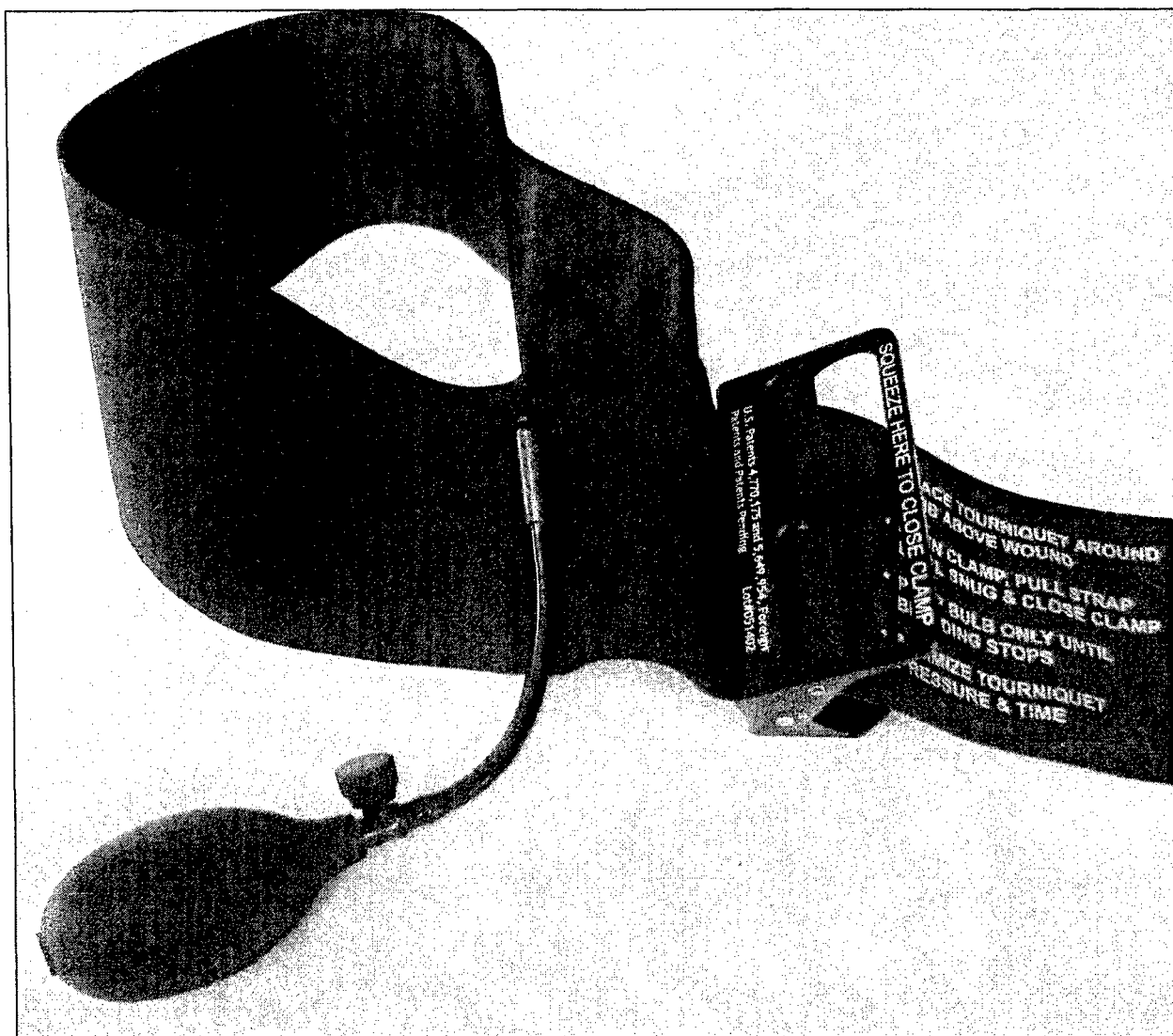


Figure 4. The Emergency Military Tourniquet (Delfi Medical Innovations). The strap is wide and secured by the clamp to the right. The bladder within the strap is inflated with the bulb to tighten the device.

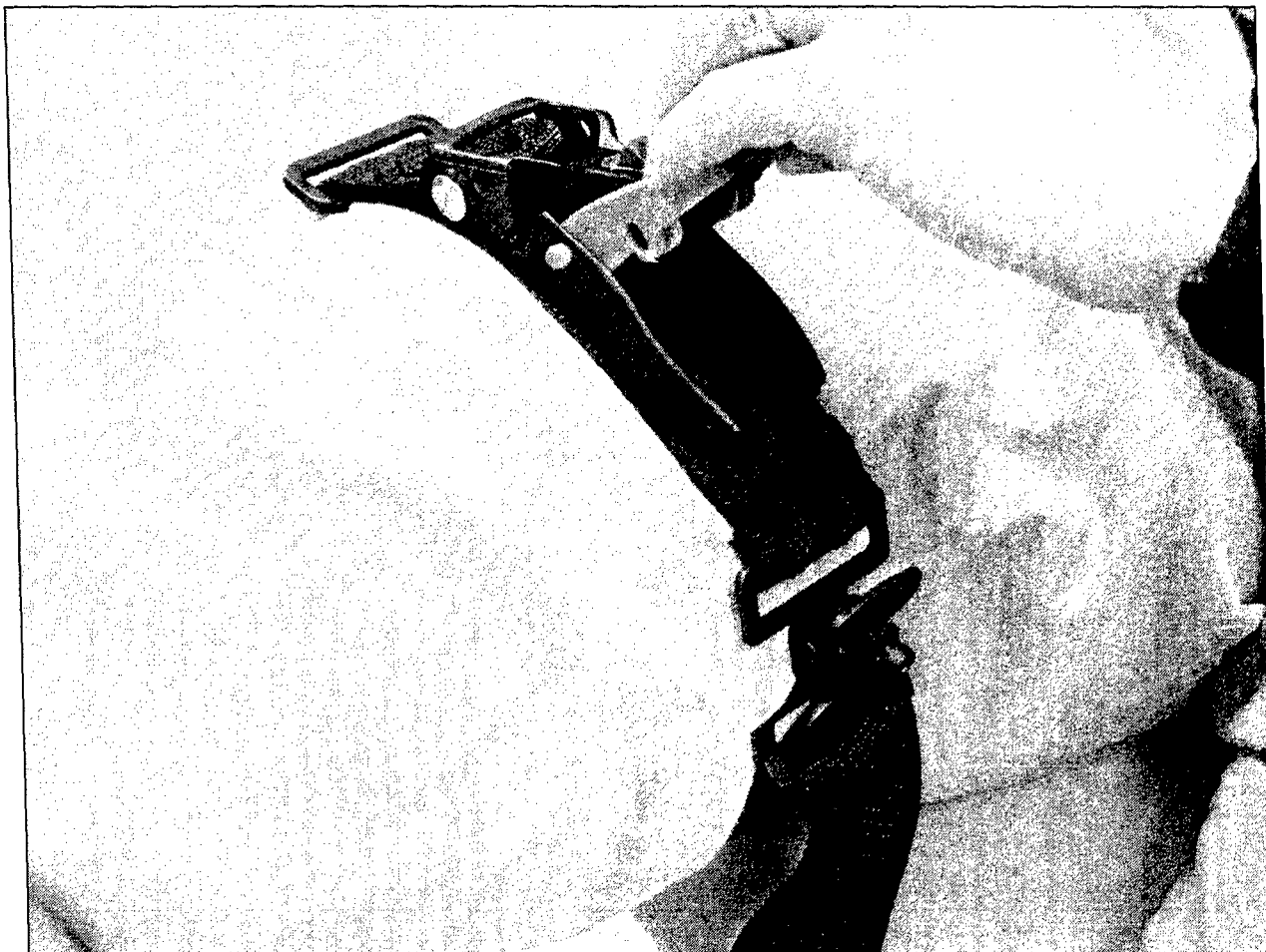
Figure 4

Figure 4. Self-Applied Tourniquet System (SATS). The cam system used in this tourniquet provided too little excursion to reliably and effectively occlude blood flow.

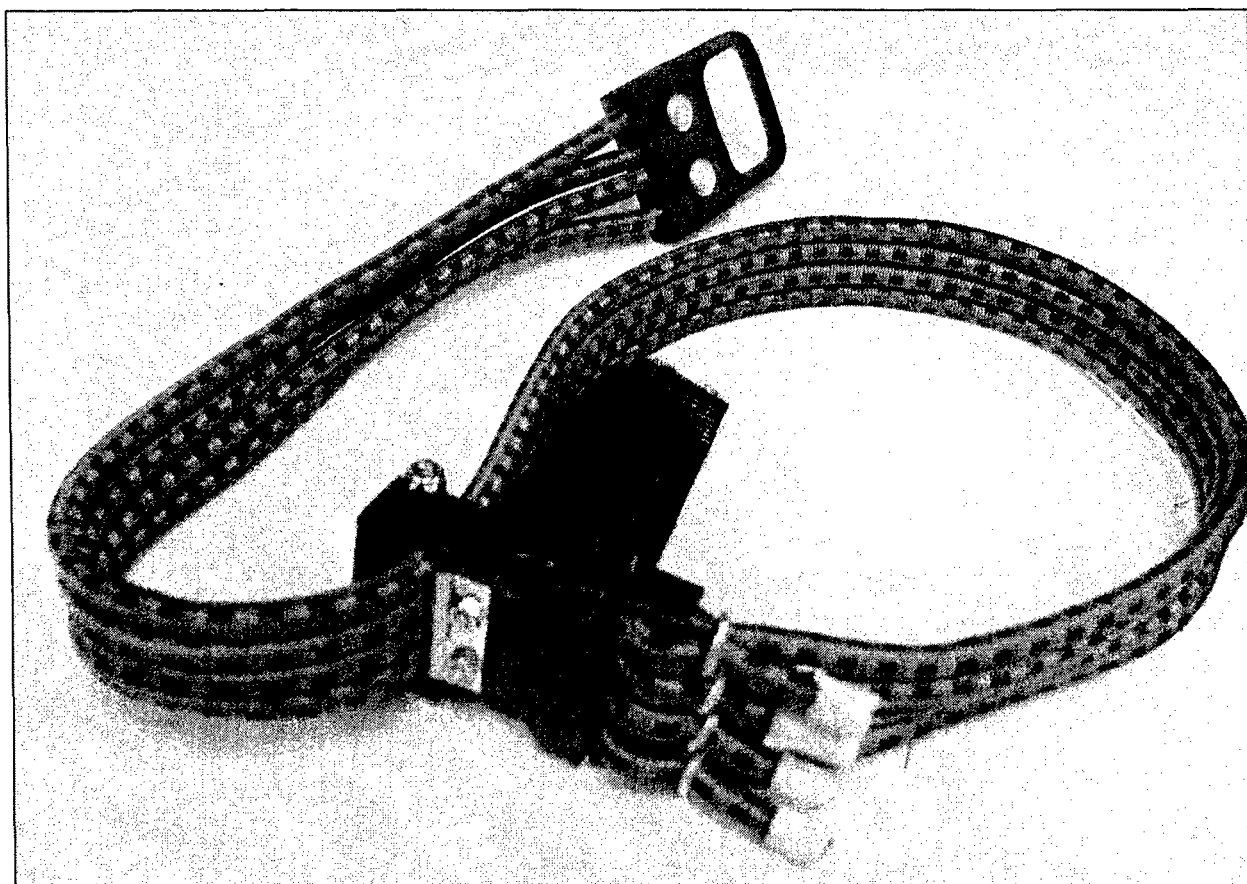
Figure 5

Figure 5. The One Handed Tourniquet (Hemodyne). Tension is created by pulling the free end through the metal jaw. This tightens but also narrows the four elastic cords. The silver plate acts to prevent the cords from slipping, but makes it very difficult to release the device.

Figure 6

Figure 6. Mechanical Advantage Tourniquet (MAT). This device malfunctioned on some trials and severely pinched the skin. At the time of this writing, both issues have been addressed by the manufacturer.

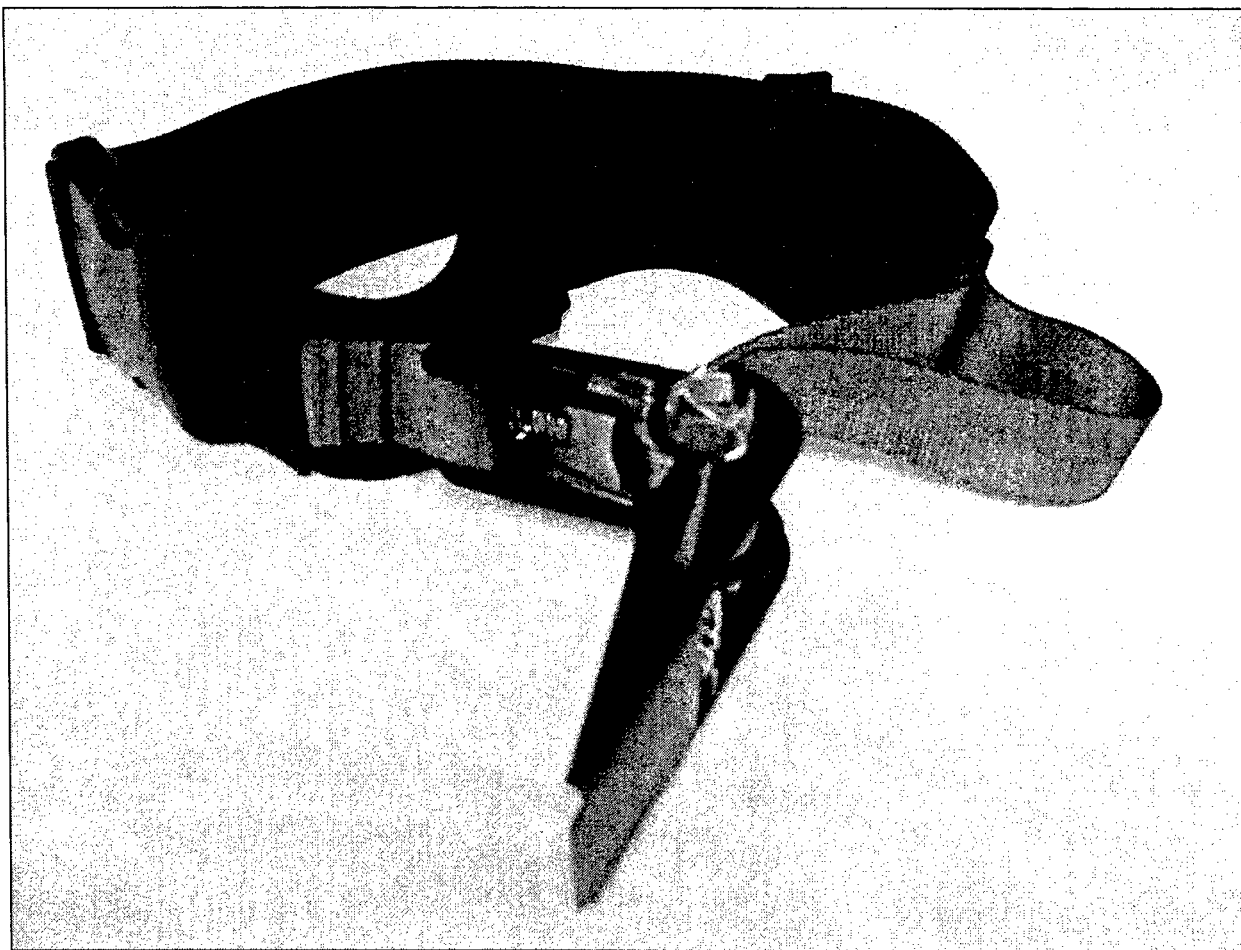
Figure 7

Figure 7. The Last Resort Tourniquet (Hammerhead). The metal portion (similar to a cargo strap) contains a cam-and-ratchet device to tighten the outer strap. This device malfunctioned in some trials.

Appendix A

Prototype Tourniquets for the Department of Defense Research On Combat Casualty Care

The Combat Casualty Care Research Program of the Medical Research and Materiel Command (USAMRMC) provides integrated capabilities for far-forward medical care to reduce mortality and morbidity associated with major battlefield wounds and injuries. The USAMRMC is seeking to test and evaluate novel prototype tourniquets for hemorrhage control on the battlefield.

Interested firms will be required execute a loan agreement with the USAMRMC to provide 10 prototype tourniquets by July 1, 2004 for test and evaluation at the United States Army Institute of Surgical Research. In return, each firm will be provided the test results on their tourniquet.

The tourniquet must meet the following requirements: 1) Complete occlusion of arterial blood flow in a thigh (thigh circumference = 26.7 inches); 2) Easy application to either the upper and lower extremity in less than 1 minute (in a tactical environment) with a minimum of familiarization; 3) Must not slip (towards wound) during tightening or following application; 4) Capable of easy release and re-application; 5) Must be less than 230 grams; 6) No external power requirement, i.e., batteries; and 7) A self-life of 10 yr. Other features that are desirable, but not required are: 1) No less than 2 inches in width; 2) One-handed, self-application to upper extremity; 3) Capability to apply to trapped limbs; 4) Protection from over-tightening; and 5) Have a predicted cost for large scale production not to exceed \$25/unit. The Government has limited resources, so only the best qualified products may be tested. No tourniquet equal to or less than 1 inch in width will be considered. Efficacy as well as overall size, weight, and cost will be major considerations. A letter of intent (LOI) expressing your interest and describing product to be offered must be e-mailed to Cheryl Miles at cheryl.miles@amedd.army.mil not later than April 15, 2004.